

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC. and	)	
BAYER HEALTHCARE LLC,	)	
	)	
Plaintiffs,	)	
	)	C. A. No. 05-349-GMS
v.	)	
	)	JURY TRIAL DEMANDED
BAXTER INTERNATIONAL INC. and	)	
BAXTER HEALTHCARE CORPORATION,	)	<b>PUBLIC VERSION</b>
	)	
Defendants.	)	
	)	
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BAXTER HEALTHCARE CORPORATION,	)	
	)	
Counterclaimant,	)	
	)	
v.	)	
	)	
TALECRIS BIOTHERAPEUTICS, INC. and	)	
BAYER HEALTHCARE LLC,	)	
	)	
Counterdefendants.	)	

**DECLARATION OF ANNE M. ROGASKI IN SUPPORT OF DEFENDANTS BAXTER  
INTERNATIONAL INC.'S AND BAXTER HEALTHCARE CORPORATION'S  
MOTION FOR RECONSIDERATION OF MEMORANDUM AND ORDER GRANTING  
MOTION FOR SUMMARY JUDGMENT THAT THE CLAIMS OF THE '191 PATENT  
ARE NOT INDEFINITE**

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*Attorneys for Defendant Baxter International  
Inc. and Defendant/Counterclaimant  
Baxter Healthcare Corporation*

Dated: July 2, 2007  
Public Version: July 5, 2007

I, Anne M. Rogaski, declare:

1. I am a partner at the law firm of Townsend and Townsend and Crew LLP and one of the counsel of record for Defendant Baxter International Inc. and Defendant/Counterclaimant Baxter Healthcare Corporation (collectively "Baxter"). I make this declaration of my personal knowledge.

2. True and correct copies of pages 330-339 and 352-353 from 10A Charles A. Wright, Arthur R. Miller & Mary K. Kane, *Federal Practice and Procedure*, § 2720 (1998) are attached hereto as Exhibit A.

3. True and correct copies of Plaintiffs' confidential hemolytic test results (DTX0135, DTX0136) are attached hereto as Exhibit B.

4. True and correct copies of Baxter's confidential hemolytic test results (DTX0138, and DTX0139) are attached hereto as Exhibit C

5. True and correct copies of Plaintiffs' confidential C1q test results (PTX0273 and PTX0274) are attached hereto as Exhibit D.

6. True and correct copies of pages 68-75 of the confidential Expert Report of Thomas J. Kindt Concerning U.S. Patent No. 6,686,191 dated January 10, 2007 (without exhibits) (PTX0238) are attached hereto as Exhibit E.

7. True and correct copies of pages 82, 86-90, and 94-97 of the highly confidential deposition transcript from the February 28, 2007 deposition of Thomas J. Kindt, Ph.D. are attached hereto as Exhibit F.

8. Had Plaintiffs filed a cross-motion for summary judgment, Baxter's invalidity expert, Dr. Thomas Kindt, was prepared to testify and/or submit a supporting declaration as to many factual issues that would have undermined Plaintiffs' claim of no indefiniteness.

9. For example, Dr. Kindt would have testified and/or submitted a supporting declaration that there was no single level of acceptability understood by persons of skill in the art at the time the '191 patent application was filed; in fact, there were different levels of "acceptability" disclosed in the prior art. *See, e.g.*, Exs. E at pp. 68-72; F at 89:14-90:2.

10. Dr. Kindt would have further testified and/or submitted a supporting declaration that the results of tests such as C1q tests cannot be compared to the results of tests used in the prior art to measure ACA "acceptability" because the different assays measure different things – e.g., C1q tests measure C1q binding, which is *not* the same as ACA; moreover, Plaintiffs never even purport to express what C1q binding level/value is "acceptable" in any of their assertions. *See, e.g.*, Ex. E at pp. 68-70.

11. Dr. Kindt would have further testified and/or submitted a supporting declaration that ACA tests must be validated for a particular product; in other words, results from validated ACA tests for a particular product cannot be compared to levels of "acceptability" such as those shown in the examples in the '191 patent. *See, e.g.*, Exs. E at pp. 72-73; F at 95:22-96:19.

12. Dr. Kindt would have further testified and/or submitted a supporting declaration that if a manufacturer had a product with a known ACA level, comparing its ACA against the prior art would not allow that manufacturer to determine whether or not its ACA level was acceptable. *See, e.g.*, Exs. E at pp. 68-73; F at 96:20-97:21.

13. Dr. Kindt would have further testified and/or submitted a supporting declaration that persons of ordinary skill in the art would need identification of the specific test used to measure ACA in order to determine if a product infringes. *See, e.g.*, F at 82:7-25; 86:24-87:14.

14. Dr. Kindt would have further testified and/or submitted a supporting declaration that a person of ordinary skill in the art would not equate FDA release limits with "acceptable level" as used in the '191 patent. *See, e.g.,* Exs. E at pp. 74-75; F at 88:2-20, 90:7-15, 94:2-5.

15. In addition to the evidence presented by and through Dr. Kindt, Baxter would have offered documentary evidence that different ACA or complement tests give different results, some of which may appear to fall within the asserted claim and others which do not fall within the claim, including:

- Plaintiffs' Clq and hemolytic tests which give two different results. *Compare* Rogaski Decl., Ex. B *with* Ex. D.
- The Rousell paper which shows that the determination of whether an ACA level is "acceptable" depends upon the parameters of the test that is run. A true and correct copy of Rousell, *et al.*, "Anticomplementary Activity and the Safety of Intravenous Immunoglobulin," *Clin. Therapeutics* 11(1): 143-150 (1989) is attached hereto as Exhibit G.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct. Executed this 2nd day of July, 2007 at Palo Alto, California.

  
\_\_\_\_\_  
Anne M. Rogaski

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Public Version: July 5, 2007

# **Exhibit A**

**§ 2720 SUMMARY JUDGMENT PROCEEDINGS**  
**Rule 56**

**Ch. 8**

**Third Circuit in *Rains v. Cascade Industries, Inc.***<sup>3</sup>

Cross-motions are no more than a claim by each side that it alone is entitled to summary judgment, and the making of such inherently contradictory claims does not constitute an agreement that if one is rejected the other is necessarily justified or that the losing party waives judicial consideration and determination whether genuine issues of material fact exist. If any such issue exists it must be disposed of by a plenary trial and not on summary judgment.<sup>4</sup>

In short, the mere fact that both parties seek summary judgment does not constitute a waiver of a full trial or the right to have the

*U.S. v. Curtis-Nevada Mines, Inc.*,  
 D.C.Cal.1976, 415 F.Supp. 1373, re-  
 versed on the merits C.A.9th, 1980,  
 611 F.2d 1277.

**But see**

When both parties have filed a stipulation of facts and the court is of the opinion that the parties, by their stipulation, have submitted all the evidence that is available and because of this fact, the result of either determining the cause on cross-motions for summary judgment or the merits would be the same, the court may deem the cross-motions as an admission that there was no question of fact remaining. *Garrett Freightlines, Inc. v. U. S.*, D.C.Idaho 1964, 236 F.Supp. 594.

**Tenth Circuit**

The fact that there were joint motions for summary judgment did not result in any waiver of a judicial determination of whether a material issue of fact existed on either side of the case; however, the filing of cross-motions under Rule 56 raised the inference that there was no evidence other than the pleadings and supporting instruments to be considered and so the trial court was required only to examine those materials in ascertaining whether an issue of material fact existed. *SEC v. American Commodity Exchange, Inc.*, C.A.10th, 1976, 546 F.2d 1361.

*International Bhd. of Elec. Workers v. WGN of Colorado*, D.C.Colo.1985, 615 F.Supp. 64, 66, citing *Wright, Miller & Kane*.

*Midland Mortgage Co. v. U.S.*, D.C.Okla. 1983, 576 F.Supp. 101, 106, citing *Wright & Miller*.

*Keller v. California Liquid Gas Corp.*, D.C.Wyo.1973, 363 F.Supp. 123.

**But see**

"Cross motions under Rule 56, F.R.Civ. P., give rise to the inference there is no evidence other than the pleadings and supporting instruments to be considered." *H. B. Zachry Co. v. O'Brien*, C.A.10th, 1967, 378 F.2d 423.

**Eleventh Circuit**

*Airport Taxi Cab Advisory Comm. v. City of Atlanta*, D.C.Ga.1983, 584 F.Supp. 961, 963, citing *Wright, Miller & Kane*.

**State cases**

*Wyoming v. Homar*, Wyo.1990, 798 P.2d 824, 825, citing *Wright, Miller & Kane*.

*Brown v. Credit Center, Inc.*, Miss.1983, 444 So.2d 358, 363, citing *Wright, Miller & Kane*.

**3. *Rains* case**

C.A.3d, 1968, 402 F.2d 241.

**4. Not constitute agreement**

402 F.2d at 245 (per Freedman, J.).



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CROSS-MOTIONS

§ 2720  
Rule 56

case presented to a jury.<sup>5</sup>

There are basically three reasons why cross-motions under Rule 56 do not necessarily indicate that the case is ripe for final resolution and the entry of judgment. First, the determination whether a genuine issue concerning a material fact exists is itself a question of law that must be decided by the court. It does not depend upon what either or both of the parties may have thought about the matter.<sup>6</sup>

#### 5. Not waiver

McDonald, Summary Judgments, 1952,  
30 Texas L.Rev. 285, 303.

#### 6. Not depend on parties

Griffis v. Delta Family-Care Disability,  
C.A.11th, 1984, 723 F.2d 822, 824, cit-  
ing Wright & Miller, certiorari de-  
nied 104 S.Ct. 3514, 467 U.S. 1242, 82  
L.Ed.2d 823.

Cram v. Sun Ins. Office, Ltd., C.A.4th,  
1967, 375 F.2d 670.

"In this case, this Court is again con-  
fronted with the confusion which  
follows the filing of motions for  
summary judgment by plaintiff and  
defendant respectively. Again it is  
reiterated that such a situation does  
not parallel that where both parties  
file motions for directed verdict. In  
the latter instance, each party is  
held to agree that there is no dis-  
puted question of fact and that the  
case is to be decided on the princi-  
ples of law. In contrast, by defini-  
tion, a summary judgment cannot be  
granted if there be a disputed ques-  
tion of material fact. This determi-  
nation does not depend upon what  
either or both parties may have  
thought about the matter." Brawner  
v. Pearl Assurance Co., C.A.9th,  
1958, 267 F.2d 45, 46 (per Fee, J.).

Central States SE & SW Areas Pension  
Fund v. Ekco Prods., Inc., D.C.Ill.  
1984, 581 F.Supp. 374, 377, citing  
Wright & Miller.

Banco Nacional de Desarrolla v. Mellon  
Bank, N.A., D.C.Pa.1983, 558 F.Supp.  
1265, 1268, citing Wright & Miller,

reversed on the merits C.A.3d, 1984,  
726 F.2d 87.

Wright v. Credit Bureau of Georgia, Inc.,  
D.C.Ga.1982, 548 F.Supp. 591, 593,  
citing Wright & Miller.

Meyr v. Board of Educ. of Affton School  
Dist., D.C.Mo.1977, 435 F.Supp. 1155,  
1159, citing Wright & Miller, af-  
firmed C.A.8th, 1978, 572 F.2d 1229.

Wilner v. U. S., D.C.N.Y.1961, 195  
F.Supp. 786, 790.

#### See also

Demandre v. Liberty Mut. Ins. Co.,  
C.A.5th, 1959, 264 F.2d 70.

Smith v. New England Mut. Life Ins.  
Co., 1992, 827 P.2d 635, 643, 72 Ha-  
waii 531, 547, quoting Wright, Mil-  
ler & Kane.

#### But compare

Cross-motions for summary judgment  
authorize the court to assume that  
there is no evidence that needs to be  
considered other than that which has  
been filed by the parties. Harrison  
Western Corp. v. Gulf Oil Co.,  
C.A.10th, 1981, 662 F.2d 690.

H. B. Zachry Co. v. O'Brien, C.A.10th,  
1967, 378 F.2d 423.

Garrett Freightlines, Inc. v. U. S.,  
D.C.Idaho 1964, 236 F.Supp. 594.

Dell Publishing Co. v. Summerfield,  
D.C.D.C.1961, 198 F.Supp. 843, af-  
firmed per curiam sub nom. Dell Pub-  
lishing Co. v. Day, C.A.D.C.1962, 303  
F.2d 766.

Olenick v. Brucker, D.C.D.C.1959, 173  
F.Supp. 493, order set aside per cu-  
riam C.A.D.C.1959, 273 F.2d 819.

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Second, a party may argue that no issue exists in the hope that his legal theory will be accepted, but at the same time the movant may maintain that there is a genuine factual dispute in the event his theory is rejected or the opponent's is adopted.<sup>7</sup> It should be remembered that a party moving for summary judgment concedes the absence of a factual issue and the truth of the nonmoving party's allegations only for purposes of his own motion.<sup>8</sup> It follows

### 7. Opponent's theory

The contention of one party that there are no issues of material fact sufficient to prevent the entry of judgment in its favor does not bar that party from asserting that there are issues of material fact sufficient to prevent the entry of judgment as a matter of law against it. *Zook v. Brown*, C.A.7th, 1984, 748 F.2d 1161.

*Nafco Oil & Gas, Inc. v. Appleman*, C.A.10th, 1967, 380 F.2d 323.

*Cram v. Sun Ins. Office, Ltd.*, C.A.4th, 1967, 375 F.2d 670.

The government, which had taken the position that no genuine material factual issue existed only for the purpose of presenting its theory that the fact that payments were to be made over a period exceeding ten years made the payments taxable to the wife, was not estopped by its motion for summary judgment to claim the existence of a material fact after its motion was overruled and the wife, seeking a refund of income tax paid, interposed her own motion for summary judgment. *U. S. v. Mills*, C.A.10th, 1966, 372 F.2d 693.

*American Fidelity & Cas. Co. v. London & Edinburgh Ins. Co.*, C.A.4th, 1965, 354 F.2d 214.

*Allied Mut. Ins. Co. v. Lysne*, C.A.8th, 1963, 324 F.2d 290, 292.

*Garrett Biblical Institute v. American Univ.*, C.A.D.C.1947, 163 F.2d 265.

"[A]lthough a defendant may, on his own motion, assert that, accepting his legal theory, the facts are undisputed, he may be able and should always be

allowed to show that, if plaintiff's legal theory be adopted, a genuine dispute as to a material fact exists." *Walling v. Richmond Screw Anchor Co.*, C.C.A.2d, 1946, 154 F.2d 780, 784 (per Frank, J.), certiorari denied 66 S.Ct. 1383, 328 U.S. 870, 90 L.Ed. 1640.

In *Gould v. American Hawaiian S.S. Co.*, D.C.Del.1970, 319 F.Supp. 795, 802, plaintiff moved for a partial summary judgment and defendant made a cross-motion for summary judgment but the court noted that "both sides contend that the Court cannot grant summary judgment for the other side; plaintiffs on the grounds that they have a right to take the issue of materiality to the jury and the defendants (apparently) on the ground that there are disputed issues of fact."

### See also

*American Mfrs. Mut. Ins. Co. v. American Broadcasting-Paramount Theatres, Inc.*, C.A.2d, 1967, 388 F.2d 272, 279.

*Century Medical Plaza v. Goldstein*, 1979, 596 P.2d 721, 723, 122 Ariz. 583, citing *Wright & Miller*.

### 8. Purposes of own motion

*McKenzie v. Sawyer*, C.A.D.C.1982, 684 F.2d 62.

*Carlson v. New Hampshire Dep't of Safety*, C.A.1st, 1979, 609 F.2d 1024, 1025 n. 1, citing *Wright & Miller*.

*Johnston v. Holiday Inns, Inc.*, C.A.1st, 1979, 595 F.2d 890, 895, citing *Wright & Miller*.



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## CROSS-MOTIONS

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*Cram v. Sun Ins. Office, Ltd.*, C.A.4th,  
1967, 375 F.2d 670.

*U.S. v. Mills*, C.A.10th, 1966, 372 F.2d  
693.

*Allied Mut. Ins. Co. v. Lysne*, C.A.8th,  
1963, 324 F.2d 290, 292.

In *Camilla Cotton Oil Co. v. Spencer Kellogg & Sons, Inc.*, C.A.5th, 1958, 257 F.2d 162, the appellate court reversed a summary judgment for plaintiff as to a counterclaim and went on to hold that plaintiff's concession that defendant was entitled to an offset in a certain amount was made only for purposes of its summary judgment motion and that issue would be reopened on remand.

When defendant in an action by the owner of a patent for infringement and unfair competition moved for summary judgment on the specific ground that as a matter of law the patent was invalid, defendant admitted that there was no genuine issue of material fact for the purpose of its motion and on the issue presented by its motion, but did not make that admission as to all the issues raised in its pleadings. Therefore, in the absence of stipulations or admissions showing the absence of any dispute on other issues raised by the pleadings, it was improper for the court to enter judgment for the owner. *Prepo Corp. v. Pressure Can Corp.*, C.A.7th, 1956, 234 F.2d 700, certiorari denied 77 S.Ct. 132, 352 U.S. 892, 1 L.Ed.2d 87.

"Each [party], in support of his own motion, may be willing to concede certain contentions of his opponent, which concession, however, is only for the purpose of the pending motion. If the motion is overruled, the concession is no longer effective. Appellants' concession that no genuine issue of fact existed was made in support of its own motion for summary judgment. We do not think that the concession continues over into the Court's separate consideration of ap-

pellee's motion for summary judgment in his behalf after appellants' motion was overruled." *Begnaud v. White*, C.A.6th, 1948, 170 F.2d 323, 327 (per Miller, J.).

*Lewis v. Atlas Corp.*, C.C.A.3d, 1946, 158 F.2d 599.

A concession made for purposes of a motion for a judgment on the pleadings cannot be used to support the opposing party's summary judgment motion. *M. Snower & Co. v. U. S.*, C.C.A.7th, 1944, 140 F.2d 367.

*Oliver v. McClung*, D.C.Ind.1995, 919 F.Supp. 1206, 1222, quoting *Wright, Miller & Kane*.

*Eimers v. Honda Motor Co.*, D.C.Pa. 1992, 785 F.Supp. 1204, 1208, citing *Wright, Miller & Kane*.

*Applications Research Corp. v. Naval Air Devel. Center*, D.C.Pa.1990, 752 F.Supp. 660, 666, citing *Wright, Miller & Kane*.

*Young v. Southwestern Bell Tel. Co.*, D.C.Ark.1969, 309 F.Supp. 475, affirmed per curiam C.A.8th, 1970, 424 F.2d 256.

*Newport Fed. Savs. & Loan Ass'n v. U.S.*, D.C.Ark.1966, 259 F.Supp. 82.

*New England Foundation Co. v. F. H. McGraw & Co.*, D.C.R.I.1953, 113 F.Supp. 246, reversed on other grounds C.A.1st, 1954, 210 F.2d 62 (court erroneously cites the *Fox* case, described below, to support this proposition).

"Where, as here, both sides move for summary judgment, each, for the purpose of his motion, concedes and affirms that there is no issue of fact to be decided." *U. S. v. Haynes School Dist. No. 8*, D.C.Ark.1951, 102 F.Supp. 843, 848.

In *Lichten v. Eastern Air Lines, Inc.*, D.C.N.Y.1949, 87 F.Supp. 691, 693, affirmed on other grounds C.A.2d, 1951, 189 F.2d 939, plaintiff sued an air carrier for loss of baggage containing valuable jewelry. Both parties moved

## § 2720 SUMMARY JUDGMENT PROCEEDINGS

### Rule 56

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that the legal theories the movant advances in support of a Rule 56 motion and the assertion that there is no issue of material fact may not be used against the movant when the court rules on his adversary's motion. For example, a defendant moving for summary judgment on the ground that the claim is barred by the statute of limitations may contend that there is no issue of fact as to that defense, but if the defense is held insufficient as a matter of law, defendant still may argue that there is an issue of fact as to liability on the claim asserted against him. On the other hand, if a party concedes that the facts are not disputed and makes no attempt to file counter-affidavits in response to the opponent's cross-motion under Rule 56, summary judgment, if otherwise proper, may be entered against him.<sup>9</sup>

for summary judgment. Defendant's motion was based on the argument that as a matter of law it was not liable for the loss. The court noted: "Defendant denies knowledge or information as to the existence or value of the jewelry in the bag, or the alleged misdelivery of the bag, but concedes the existence of these facts for the purposes of its motion for summary judgment. Defendant does not admit the existence of the aforementioned allegations for the purpose of a ruling on plaintiff's motion."

#### See also

*Johnston v. Holiday Inns, Inc.*, C.A.1st, 1979, 595 F.2d 890, 895, citing *Wright & Miller*.

*Fireman's Fund Mortgage Corp. v. Allstate Ins. Co.*, Alaska 1992, 838 P.2d 790, 791, citing *Wright, Miller & Kane*.

*Kodiak Island Borough v. Large*, Alaska 1981, 622 P.2d 440, 446, citing *Wright & Miller*.

#### But see

In *Lloyd v. Franklin Life Ins. Co.*, C.A.9th, 1957, 245 F.2d 896, 897, the court rejected defendant's argument that it made an admission only for purposes of its own summary judgment motion. Judge Fee, speaking for

the court, said: "A concession of fact on motion for summary judgment establishes the fact for all time between the parties. The party cannot gamble on such a conditional admission and take advantage thereof when judgment has gone against him. This Court will not emasculate thus the efficient devices of summary judgment."

When defendant filed a motion for summary judgment and plaintiff filed a counter-motion and supporting affidavits, plaintiff thereby conceded that there was no genuine issue as to any material fact and therefore judgment on the pleadings was proper. *Fox v. Johnson & Wimsatt, Inc.*, C.A.D.C. 1942, 127 F.2d 729.

#### 9. Judgment may be proper

Statement by appellant's counsel on oral argument that basically there was no dispute as to the facts and that the appellant therefore had filed no counter-affidavits constituted a concession that the facts were not in dispute so that the district court properly could consider the entry of summary judgment for the opposing party. *U. S. v. Dooley*, C.A.5th, 1970, 424 F.2d 1067.

*U.S. v. New Castle County*, D.C.Del. 1989, 727 F.Supp. 854, 860, citing *Wright, Miller & Kane*.

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## CROSS-MOTIONS

§ 2720  
Rule 56

The third reason that cross-motions must be considered separately and should not be interpreted necessarily to mean that judgment should be entered on one of them is that each party, as a movant for summary judgment, bears the burden of establishing that no genuine issue of material fact exists and that he is entitled to a judgment as a matter of law.<sup>10</sup> The fact that one party fails to satisfy that burden on his own Rule 56 motion does not automatically indicate that the opposing party has satisfied his burden and should be granted summary judgment on the other motion.<sup>11</sup> The court must rule on each party's motion on an individual and separate basis, determining, for each side, whether a judgment may

**Compare**

As a general rule, the filing by both parties of opposing motions for summary judgment will not warrant the court's granting either party's motion if indeed there exists a genuine factual dispute concerning a material issue; however, when the parties proceed on the same legal theory and on the same material facts, the basis for the rule disappears. *Schlytter v. Baker*, C.A.5th, 1978, 580 F.2d 848.

**But compare**

When plaintiffs failed to file a statement in opposition to defendant's statement of material facts as to which defendant contended there were no genuine issues for trial, defendant's assertions could be accepted as true and its motion for summary judgment granted in full, but in fairness to plaintiffs, their counsel's affidavit in support of a cross-motion for summary judgment would be treated as a statement in opposition to defendant's statement. *Schwartz v. Boston Hosp. for Women*, D.C.N.Y.1976, 422 F.Supp. 53.

**10. Movant's burden**

See § 2727.

**11. Opposing party's burden**

*Buell Cabinet Co. v. Sudduth*, C.A.10th, 1979, 608 F.2d 431, 433, citing *Wright & Miller*.

*Lowenschuss v. Kane*, C.A.2d, 1975, 520 F.2d 255.

*Rains v. Cascade Indus., Inc.*, C.A.3d, 1968, 402 F.2d 241.

*Nieves v. Intercontinental Life Ins. Co. of Puerto Rico*, D.C.Puerto Rico 1991, 763 F.Supp. 1161, 1163, citing *Wright, Miller & Kane*, reversed on other grounds C.A.1st, 1992, 964 F.2d 60.

The mere fact that plaintiff has failed to meet his burden of proof on his motion for summary judgment does not entitle the defendant to judgment on its motion for summary judgment. *Rothenberg v. Chemical Bank New York Trust Co.*, D.C.N.Y.1975, 400 F.Supp. 1299.

"Whoever has the burden of proof will lose if he fails to sustain it. Here, however, if I should decide that plaintiffs have not sustained the burden of proof, it does not follow that defendants can get summary judgment. They can not get summary judgment, as distinguished from judgment after trial, unless they meet the 'slightest doubt' test." *Steinberg v. Adams*, D.C.N.Y.1950, 90 F.Supp. 604, 608 (per Rifkind, J.).

**See also**

*Amason v. First State Bank of Lineville*, Ala.1979, 369 So.2d 547, 552, citing *Wright & Miller*.



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### Rule 56

be entered in accordance with the Rule 56 standard.<sup>12</sup> Both motions must be denied if the court finds that there is a genuine issue of material fact.<sup>13</sup> But if there is no genuine issue and one or the other

#### 12. Normal standards

*Besso v. Cummins Intermountain, Inc.*, D.C.Wyo.1995, 885 F.Supp. 1516, 1520, quoting *Wright, Miller & Kane*.

*Lucas v. Curran*, D.C.Md.1994, 856 F.Supp. 260, 264, citing *Wright, Miller & Kane*.

*Marylanders for Fair Representation, Inc. v. Schaefer*, D.C.Md.1994, 849 F.Supp. 1022, 1030, citing *Wright, Miller & Kane*.

*Federal Sav. & Loan Ins. Corp. v. Heidrick*, D.C.Md.1991, 774 F.Supp. 352, 356, quoting *Wright, Miller & Kane*.

*Johnson v. Sullivan*, D.C.Md.1991, 764 F.Supp. 1053, 1064, quoting *Wright, Miller & Kane*.

*Towne Management Corp. v. Hartford Acc. & Indem. Co.*, D.C.Md.1985, 627 F.Supp. 170, 172, quoting *Wright, Miller & Kane*.

See generally §§ 2725-2728.

#### 13. Motions denied

The court is not permitted to resolve genuine issues of material fact on a motion for summary judgment, even when both parties have filed cross-motions for summary judgment. *ITCO Corp. v. Michelin Tire Corp.*, Commercial Div., C.A.4th, 1983, 722 F.2d 42, 45 n. 3, certiorari denied 105 S.Ct. 1191, 469 U.S. 1215, 84 L.Ed.2d 337.

*Rains v. Cascade Indus., Inc.*, C.A.3d, 1968, 402 F.2d 241.

In *American Mfrs. Mut. Ins. Co. v. American Broadcasting-Paramount Theatres, Inc.*, C.A.2d, 1967, 388 F.2d 272, 279 (per Kaufman, J.), the appellate court reversed a grant of summary judgment, stating: "The instant litigation is somewhat atypical because both parties clamor for sum-

mary judgment urging that the record presents no disputed material issue of fact—as if a trial is to be avoided like the plague. But, rather typical of such 'agreements' to end the case by summary judgment, this admirable harmony does not carry over to agreement on what the 'undisputed' facts are or the permissible inferences to be drawn from them. While a substantial part (but not all) of the evidence is documentary, the parties sharply dispute the inferences to be drawn \* \* \*."

*Nafco Oil & Gas, Inc. v. Appleman*, C.A.10th, 1967, 380 F.2d 323.

*American Fidelity & Cas. Co. v. London & Edinburgh Ins. Co.*, C.A.4th, 1965, 354 F.2d 214.

*Jacobson v. Maryland Cas. Co.*, C.A.8th, 1964, 336 F.2d 72, certiorari denied 85 S.Ct. 655, 379 U.S. 964, 13 L.Ed.2d 558.

*Allied Mut. Ins. Co. v. Lysne*, C.A.8th, 1963, 324 F.2d 290, 292.

On an appeal after a trial on the merits, the court commented that an earlier Rule 56 motion properly was overruled by the trial judge when the documents and affidavits introduced by both parties on their respective summary judgment motions raised substantial issues of fact. *Utica Mut. Ins. Co. v. Rollason*, C.A.4th, 1957, 246 F.2d 105.

*Lloyd v. Franklin Life Ins. Co.*, C.A.9th, 1957, 245 F.2d 896.

*Volunteer State Life Ins. Co. v. Henson*, C.A.5th, 1956, 234 F.2d 535.

*F.A.R. Liquidating Corp. v. Brownell*, C.A.3d, 1954, 209 F.2d 375.

*Krug v. Santa Fe Pac. R. Co.*, C.A.D.C. 1946, 158 F.2d 317.

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## CROSS-MOTIONS

## § 2720

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party is entitled to prevail as a matter of law, the court will render judgment.<sup>14</sup>

*M. Snower & Co. v. U. S.*, C.C.A.7th, 1944, 140 F.2d 367.

*Wolf v. Maryland Cas. Co.*, D.C.Ill.1985, 617 F.Supp. 456, 458, citing *Wright, Miller & Kane*.

*Wausau Ins. Co. v. Valspar Corp.*, D.C.Ill.1984, 594 F.Supp. 269, 270, citing *Wright, Miller & Kane*.

*Chambers v. McLean Trucking Co.*, D.C.N.C.1981, 550 F.Supp. 1335, 1338, citing *Wright & Miller*.

*Wright v. Credit Bureau of Georgia, Inc.*, D.C.Ga.1982, 548 F.Supp. 591, 593, citing *Wright & Miller*.

Pleadings and affidavits in an action by two corporations dealing in the purchase and sale of "in the money" and "deep in the money" put and call options attacking the validity of the Federal Reserve Board's conclusion that those options would involve prohibited extensions of credit by the writer as broker presented a genuine issue of fact whether those options are exercised and whether credit in effect is being extended precluding summary judgment even though both plaintiffs and defendant had made motions for summary judgment. *Gordon & Co. v. Board of Governors of the Federal Reserve Sys.*, D.C.Mass.1970, 317 F.Supp. 1045.

In *Sonobond Corp. v. Uthe Technology, Inc.*, D.C.Cal.1970, 314 F.Supp. 878, a patent-infringement action in which defendant counterclaimed on the grounds of invalidity and patent misuse, both parties moved for summary judgment. The court held that the record presented fact issues as to patent misuse and as to infringement, precluding summary judgment for either party.

*Lewis v. Nadaline*, D.C.N.Y.1969, 47 F.R.D. 253.

*Hubner & Williams Constr. Co. v. London Guarantee & Acc. Co.*, D.C.Colo. 1967, 280 F.Supp. 288.

*Marklin v. Drew Properties Corp.*, D.C.N.Y.1967, 280 F.Supp. 176.

When the record of five actions by the United States against an insurance company on bonds conditioned to insure the departure of aliens admitted to the United States disclosed genuine triable issues of fact, the district court could not grant cross-motions for summary judgment even though both the parties had moved under Rule 56. *U.S. v. Manufacturers Cas. Ins. Co.*, D.C.N.Y.1957, 158 F.Supp. 319.

*Moxley v. Atlantic Ref. Co.*, D.C.La.1951, 99 F.Supp. 499.

*Sharpe v. Great Lakes Steel Corp.*, D.C.N.Y.1950, 9 F.R.D. 691 (summary judgment denied as to one claim but granted as to two others).

#### See also

*Dispatch, Inc. v. City of Erie*, C.A.3d, 1966, 364 F.2d 539.

*Hycon Mfg. Co. v. H. Koch & Sons*, C.A.9th, 1955, 219 F.2d 353, certiorari denied 75 S.Ct. 881, 349 U.S. 953, 99 L.Ed. 1278.

*Beacon Fruit & Produce Co. v. H. Harris & Co.*, D.C.Mass.1957, 152 F.Supp. 702 (complete absence of facts on certain issues in an antitrust action).

#### 14. Judgment granted

Summary judgment was appropriate when there was a motion and a counter-motion for summary judgment and all the parties admitted to undisputed facts and sought a declaration of law. *Brinson v. Brinson*, C.A.4th, 1964, 334 F.2d 155.

Cross-motions for summary judgment may be probative of the nonexistence of a factual dispute when they demonstrate basic agreement concerning the



# **§ 2720 SUMMARY JUDGMENT PROCEEDINGS** Rule 56

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Finally, it should be noted that when the court is ruling on cross-motions, the facts sometimes become fully developed at the hearing on the motions. When this occurs in a nonjury case the court may proceed to decide the factual issues and render a judgment on the merits without any further delay if it is clear that there is nothing else to be offered by the parties and there is no

relevant legal theories and dispositive facts. *United Nuclear Corp. v. Cannon*, D.C.R.I.1982, 553 F.Supp. 1220.

*Allen Family Corp. v. City of Kansas City, Missouri*, D.C.Mo.1981, 525 F.Supp. 38, 39, citing *Wright & Miller*.

When all the parties had moved for summary judgment and no party had raised any genuine issue of material fact, the case was appropriate for disposition by summary judgment. *Columbia Power Trades Council v. U. S. Department of Energy*, D.C.Wash. 1980, 496 F.Supp. 186.

*Thomas Pub. Co. v. Division of Human Rights*, D.C.N.Y.1978, 456 F.Supp. 1104, 1108, citing *Wright & Miller*.

The fact that defendant, which opposed plaintiff's motion for summary judgment, claimed that there were a number of factual issues did not bar the entry of summary judgment for defendant when the issues referred to all pertained to defendant's affirmative defenses. *Baeszler v. Mobil Oil Corp.*, D.C.N.Y.1973, 375 F.Supp. 1220.

When there was no dispute as to the facts, briefs and a stipulation of facts submitted by counsel were considered as supporting cross-motions for summary judgment. *Brown v. Presbyterian Ministers Fund*, D.C.Pa.1972, 340 F.Supp. 748.

*Johnson & Johnson v. Diaz*, D.C.Cal. 1971, 339 F.Supp. 60.

*Male v. Crossroads Assocs.*, D.C.N.Y. 1971, 337 F.Supp. 1190.

An action for forfeiture of an automobile presented to the court on joint motions for summary judgment on stipu-

lated facts was a proper case for the exercise of summary judgment. *U. S. v. 1957 Oldsmobile 4-Door Sedan*, D.C.Tex.1959, 173 F.Supp. 956.

*Tampa Elec. Co. v. Nashville Coal Co.*, D.C.Tenn.1958, 168 F.Supp. 456, affirmed on other grounds C.A.6th, 1960, 276 F.2d 766, reversed on other grounds, 1961, 81 S.Ct. 623, 365 U.S. 320, 5 L.Ed.2d 580 (trial court held contract invalid under Clayton Act).

*Carrothers v. Stanolind Oil & Gas Co.*, D.C.Tex.1955, 134 F.Supp. 191.

*Taylor v. Marcelle*, D.C.N.Y.1951, 97 F.Supp. 35, 36 n. 1, affirmed per curiam C.A.2d, 1952, 199 F.2d 759.

*Amaya v. Stanolind Oil & Gas Co.*, D.C.Tex.1945, 62 F.Supp. 181, 206, affirmed on other grounds C.C.A.5th, 1946, 158 F.2d 554, certiorari denied 67 S.Ct. 1191, 331 U.S. 808, 91 L.Ed. 1828.

## See also

*Simpson Bros., Inc. v. District of Columbia*, C.A.D.C.1949, 179 F.2d 430, certiorari denied 70 S.Ct. 350, 338 U.S. 911, 94 L.Ed. 561.

*Page Communications Engineers, Inc. v. Arrien*, D.C.Pa.1970, 315 F.Supp. 569.

*SEC v. American Beryllium & Oil Corp.*, D.C.N.Y.1969, 303 F.Supp. 912.

A showing by the government of a fact issue precluding summary judgment for plaintiff in a tax refund suit would not necessarily affect the government's cross-motion for summary judgment. *Cohn v. U. S.*, D.C.Ind. 1965, 240 F.Supp. 786, 790.

*Fancher v. Clark*, D.C.Colo.1954, 127 F.Supp. 452.

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prejudice in proceeding in this fashion.<sup>15</sup> As a practical matter, of course, this procedure amounts to a trial of the action and technically is not a disposition by summary judgment.

Although Rule 56 specifically states that a summary-judgment motion may be made by any party, it does not provide for situations in which neither party moves under Rule 56 and the court desires to enter summary judgment sua sponte, or in which the nonmoving party, rather than the movant, is entitled to summary judgment, but no cross-motion has been made. The question of the court's power to enter summary judgment without a motion is the same in either of these situations, but they should be examined separately as each raises some different concerns.

The major concern in cases in which the court wants to enter summary judgment without a Rule 56 motion by either party is not really one of power. As a practical matter, the court always can "invite" the appropriate party to move under Rule 56 when it thinks the case is ripe for summary disposition. Rather, the question raised by the court's action is whether the party against whom the judgment will be entered was given sufficient advance notice and an adequate opportunity to demonstrate why summary judgment should not be granted.<sup>16</sup> If no opportunity is provided, then obviously summary judgment should not be entered.<sup>17</sup> If the court

**15. Decide factual issues**

Tripp v. May, C.A.7th, 1951, 189 F.2d 198.

Ashley v. City of Anchorage, D.C.Alaska 1951, 95 F.Supp. 189, affirmed on other grounds C.A.9th, 1952, 196 F.2d 809.

When the facts relied on by each party to a patent infringement action had been fully developed by discovery and both parties moved for summary judgment, the court could decide the factual issues and then the legal issues arising therefrom. Meikle v. Timken-Detroit Axle Co., D.C.Mich.1942, 44 F.Supp. 460.

**See also**

When the court had before it on a motion and counter-motion for summary judgment all the facts that a formal trial would have produced, and there was only a conflict concerning the decisive conclusion to be drawn from the

undisputed facts, the court properly rendered summary judgment. Fox v. Johnson & Wimsatt, Inc., C.A.D.C. 1942, 127 F.2d 729.

Carqueville v. Folsom, D.C.Ill.1958, 170 F.Supp. 777, affirmed on other grounds C.A.7th, 1959, 263 F.2d 875.

**16. Primary question**

Nowlin v. Resolution Trust Corp., C.A.5th, 1994, 33 F.3d 498, 504, citing Wright, Miller & Kane.

Maravilla v. U.S., D.C.Ind.1994, 867 F.Supp. 1363, 1380, citing Wright, Miller & Kane.

Jackson v. Pollick, D.C.Mich.1990, 751 F.Supp. 132, 133 n. 1, citing Wright, Miller & Kane.

**17. No opportunity provided**

District court's failure to give sufficient notice to defendant insurer that the court might grant summary judgment

## § 2720 SUMMARY JUDGMENT PROCEEDINGS

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objective of Rule 56 to expedite the disposition of cases<sup>27</sup> and, somewhat more remotely, with the mandate of Rule 54(c) requiring the court to grant the relief to which a party is entitled "even if the party has not demanded such relief in the pleadings."<sup>28</sup> Indeed, in 1955 the Advisory Committee proposed an amendment to Rule 56(c), which was not adopted, codifying the power of the court to grant summary judgment without waiting for a cross-motion<sup>29</sup> and some states have provisions to that effect in their summary-judgment rules.<sup>30</sup>

Nonetheless, whenever the court believes that the nonmoving party is entitled to judgment, great care must be exercised to assure

### 27. Purpose of Rule 56

*Jackson v. Nassau County Bd. of Supervisors*, D.C.N.Y.1993, 818 F.Supp. 509, 536, citing *Wright, Miller & Kane*.

*Montgomery v. Scott*, D.C.N.Y.1992, 802 F.Supp. 930, 934, citing *Wright, Miller & Kane*.

*U.S. v. Franklin Fed. Savs. & Loan Ass'n*, D.C.Pa.1956, 140 F.Supp. 286.

*Hennessey v. Federal Sec. Administrator*, D.C.Conn.1949, 88 F.Supp. 664.

*Hooker v. New York Life Ins. Co.*, D.C.Ill.1946, 66 F.Supp. 313, reversed on other grounds C.A.7th, 1947, 161 F.2d 852, certiorari denied 68 S.Ct. 109, 332 U.S. 809, 92 L.Ed. 386.

"[I]t seems apparent that the rendering of a summary judgment for an opposing party in the absence of a cross-motion is in keeping with the spirit and purpose of Rule 56, that of expediting the disposition of actions in which there is no genuine issue of fact requiring a trial. The present trend of the courts, as well as the weight of authority, indicates that the advantages to be gained from an expedient disposition of many actions greatly exceeds the relatively slight danger of prejudicing a moving party." Note, *The Propriety of Rendering a Summary Judgment in Favor of a Non-Movant Under Wyoming and Federal Rules of Civil Procedure*, 1964, 19 *Wyo.L.J.* 65, 69.

### 28. Rule 54(c) mandate

*Peiffer v. Lebanon School Dist.*, D.C.Pa. 1987, 673 F.Supp. 147, affirmed C.A.3d, 1988, 848 F.2d 44.

*DuBois v. Environmental Protection Agency*, D.C.Mo.1986, 646 F.Supp. 741, reversed on other grounds C.A.8th, 1987, 820 F.2d 943.

*Service Personnel & Employees of the Dairy Indus., Teamsters Local Union No. 205 v. Carl Colteryahn Dairy, Inc.*, D.C.Pa.1977, 436 F.Supp. 341.

*Hennessey v. Federal Sec. Administrator*, D.C.Conn.1949, 88 F.Supp. 664.

*Hooker v. New York Life Ins. Co.*, D.C.Ill.1946, 66 F.Supp. 313, reversed on other grounds C.C.A.7th, 1947, 161 F.2d 852, certiorari denied 68 S.Ct. 109, 332 U.S. 809, 92 L.Ed. 386.

### 29. 1955 proposal

See the Advisory Committee Note to the proposed 1955 amendment of Rule 56(c), which is set out in the Appendix to vol. 12. None of the amendments proposed in 1955 was adopted.

### 30. State provisions

Maryland R.C.P. 610(d).

N.D.R.C.P. 56(c).

NYCPLR 3212(b). See also 4 Weinstein, Korn & Miller, *New York Civil Practice* ¶ 3212.04a.

Wis.Stat. § 802.08(6).



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that the original movant has had an adequate opportunity to show that there is a genuine issue and that the opponent is not entitled to judgment as a matter of law.<sup>31</sup> Thus an appellate court should

## 31. Great care exercised

Ramsey v. Coughlin, C.A.2d, 1996, 94 F.3d 71, 74, quoting Wright, Miller & Kane.

Sua sponte summary-judgment procedure employed by district court violated requirements of summary-judgment rule; plaintiffs had not been notified that trial court would entertain hearing on summary judgment when they appeared for trial, were afforded 30 minutes, rather than minimum period of ten days to prepare for hearing and marshal evidence in opposition to summary-judgment disposition, and "motion" for summary judgment was never reduced to writing and was never fully articulated either by defendant's counsel or by the district judge. Stella v. Town of Tewksbury, Massachusetts, C.A.1st, 1993, 4 F.3d 53, 55, citing Wright, Miller & Kane.

Bonilla v. Nazario, C.A.1st, 1988, 843 F.2d 34, 37, quoting Wright, Miller & Kane.

Shipper had adequate opportunity to show existence of genuine issue with regard to its claim against carrier under shipping contract, and failed to raise an issue, despite addressing relevant points by what appeared to be all the evidence in its possession, justifying the district court's sua sponte grant of summary judgment in favor of the carrier, subsequent to denial of the shipper's summary-judgment motion, without the necessity of the carrier filing a formal cross motion for summary judgment. National Expositions, Inc. v. Crowley Maritime Corp., C.A.1st, 1987, 824 F.2d 131, 133, citing Wright, Miller & Kane.

Although the magistrate did not notify the summary-judgment movant before the magistrate recommended sum-

mary judgment in favor of the non-moving party, the movant was given ten days to file objections to the recommendation before the district court entered final judgment, and thus, the magistrate's recommendation was sufficient notice that the district court would consider entering summary judgment for the nonmoving party. Lindsey v. U.S. Bureau of Prisons, U.S. Dep't of Justice, C.A.11th, 1984, 736 F.2d 1462, 1463, citing Wright, Miller & Kane, vacated on other grounds 1984, 105 S.Ct. 584, 469 U.S. 1082, 83 L.Ed.2d 695.

Andrews v. DuBois, D.C.Mass.1995, 888 F.Supp. 213, 220, citing Wright, Miller & Kane.

Memphis Trust Co. v. Board of Governors of the Fed. Reserve Sys., C.A.6th, 1978, 584 F.2d 921, 924, quoting Wright & Miller.

One concern in granting summary judgment to the opposing party is that the movant be given an adequate opportunity to adduce factual material which raises a substantial question of the veracity or the completeness of the other side's case. McKenna v. Peekskill Housing Authority, D.C.N.Y.1980, 497 F.Supp. 1217.

## See also

Plaintiff had adequate notice of the court's consideration of summary judgment on a particular issue when the issue was implicitly raised by plaintiff itself in plaintiff's motion for partial summary judgment, defendant alleged total deficiency of evidence on the issue in response to plaintiff's motion for partial summary judgment, and the issue was unambiguously raised in the other defendant's motion for summary judgment. Howell Petro-

# **EXHIBIT B**



**THIS EXHIBIT HAS BEEN  
REDACTED IN ITS ENTIRETY**

# EXHIBIT C

**THIS EXHIBIT HAS BEEN  
REDACTED IN ITS ENTIRETY**

# **EXHIBIT D**

**THIS EXHIBIT HAS BEEN  
REDACTED IN ITS ENTIRETY**



# **EXHIBIT E**

**THIS EXHIBIT HAS BEEN  
REDACTED IN ITS ENTIRETY**

# **EXHIBIT F**

**THIS EXHIBIT HAS BEEN  
REDACTED IN ITS ENTIRETY**

# **Exhibit G**



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CLINICAL THERAPEUTICS/VOL. 11, NO. 1, 1989

**Anticomplementary Activity and the Safety  
of Intravenous Immunoglobulin***Ralph H. Rousell, M.D., M.Sc., Miriam D. Budinger, M.D.,  
Douglas C. Keppler, B.A., and Rae Victor, Ph.D.**Cutter Biological, Miles Inc, Berkeley, California**Takeyoshi Minaga, M.D., Ph.D.**Bayer Yakuhin, Ltd, Osaka, Japan***ABSTRACT**

Quality assurance release levels for anti-complementary (AC) activity of a non-modified intravenous immunoglobulin (IGIV, pH 4.25) were reviewed over a period of one year and nine months in an attempt to correlate the incidence of complement-mediated-type adverse reactions with the AC level. Over 200 lots and ten possible complement-mediated side effects were evaluated. No correlation was found. A similar evaluation was made of a prospective study in which three lots of IGIV, pH 4.25 (one with a low, one with a mid-range, and one with a high AC activity) were used; again no correlation was found. Finally, a comparison was made between the AC activity assay used to release IGIV, pH 4.25 and an alternative AC activity assay designed for a highly modified IGIV preparation. It was demonstrated that the AC activity assay designed for the modified preparation and its assay limits were unsuitable in attempting to define AC activity of the nonmodified preparation.

**INTRODUCTION**

The ability to fractionate human blood plasma into its component parts<sup>1-5</sup> enabled Barandun and his colleagues<sup>6</sup> in 1962 to investigate patients' intolerance to intravenous administration of the human gamma globulin fraction. Using a standard gamma globulin preparation intended for intramuscular use, they showed that only 13% of subjects without antibody deficiency developed a reaction on intravenous administration, whereas 92% of patients with antibody deficiency developed a reaction. The investigators felt it was unlikely that the reactions seen were due to direct antigen-antibody reaction—the recipients' antibodies reacting with antigens present in the gamma globulin concentrate—since patients with immune deficiency are unable to form antibodies.

They suggested that the reactions could be due to antigens in the recipient organism reacting with antibodies of the administered gamma globulin preparation, or that certain gamma globulin prepara-

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**DEPOSITION  
EXHIBIT**

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USDC, District of Delaware  
Civil Action No. 05-349-GMS

BXTR015925

Defendant Exhibit No.: 43

Date Admitted: \_\_\_\_\_

By: \_\_\_\_\_

## CLINICAL THERAPEUTICS

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tions or certain lots of such preparations might have an intrinsic ability to activate the complement system when given intravenously. The latter mechanism might be explained by aggregated gamma globulins which fix complement by a similar mechanism to antigen-antibody complexes. Measures that might be taken to treat the standard gamma globulin preparation and render it less likely to spontaneously fix complement in the absence of antigen were presented.

A major characteristic of current gamma globulin preparations that have been rendered safe for intravenous use is either minimal anticomplementary (AC) activity or the absence of AC activity.<sup>7-9</sup> It is axiomatic, therefore, that an appropriate test for AC activity is included in the quality assurance battery required for release of the different intravenous immunoglobulin preparations.

We reviewed the data of certain anticomplementary activity assays used to release an intravenous immunoglobulin rendered safe for intravenous infusion by stabilization at pH 4.25 (IGIV, pH 4.25).<sup>10</sup> The AC activity was correlated against complement-type mediated adverse reactions that were reported spontaneously or observed during clinical investigations. We also evaluated an alternative assay specifically developed to measure AC activity of nonmodified intravenous immunoglobulin (IGIV, pH 4.25) to determine whether this assay and its limits could be used to assess the safety of the preparation for intravenous administration.

## PATIENTS AND METHODS

Each patient in this study received infusions of an intravenous immunoglobulin fractionated from human blood plasma by

the Cohn-Oncley fractionation method and then stabilized in solution at a pH of 4.25.<sup>10</sup> The number of lots used during the period of spontaneous reporting exceeded 200 and were freely available on the market. Clinical product research (PR) lots were used for patients in the surveillance study.

Two groups of patients were examined for possible complement-mediated adverse reactions. All untoward effects of the first group (group 1) considered attributable to administration of IGIV, pH 4.25 were spontaneously reported to Cutter Biological between the period of March 1986 and December 1987.

The second group (group 2) was comprised of 30 patients at two centers participating in a surveillance study. All 30 patients had primary immune deficiency (14 patients with X-linked agammaglobulinemia, 14 patients with common variable agammaglobulinemia, and two patients with Wiskott-Aldrich syndrome). The patients were randomly allocated to receive monthly infusions (400 mg/kg) of IGIV, pH 4.25. Each patient received four infusions from each of three different lots. A change of lot was made after the first four months and again after the second four months, with the third lot being administered in the last four months. The three lots used were chosen deliberately to have a high AC activity (PR 3025), a mid-range AC activity (PR 3032), and a low AC activity (PR 3055), as determined by *in vitro* AC activity Method 1. The AC activity of all three lots was within the acceptable AC activity range for this assay. A total of 342 infusions were administered. The average infusion time was  $1.68 \pm 0.49$  (SD) hours; the average dosage administered was 399 mg/kg and the average volume given was 401 ml.

## Assays for

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R.H. ROUSELL ET AL.

### Assays for Anticomplementary Activity

#### Method 1

Compliance with the AC activity specification in accordance with the Cutter Biological AC test is required for all lots of IGIV, pH 4.25 released to the market, as well as those used in the definitive surveillance study. This assay consists of addition of one volume of two  $\text{CH}_{50}$  units of guinea pig complement to an equal volume of sequential dilutions of test material in an appropriately buffered solution. The appropriate dilutions of hemolysin and complement are determined by titration prior to running the assay. The diluted test samples are allowed to react with complement for two hours at  $37^\circ\text{C}$ . After incubation, sensitized sheep red blood cells are added and percent inhibition of hemolysis determined. The AC values are based upon the amount of test material that produces 50% inhibition of hemolysis. Reference standards are run with each assay to verify the performance of the test. The release limit for the test is less than 25 units  $\text{CH}_{50}/\text{ml}$  of product.

#### Method 2

For comparative purposes, complement assays were also performed on ten of the marketed lots, using a complement assay originally designed to assess complement activity of an intravenous immunoglobulin preparation rendered safe for intravenous administration by pepsin digestion. This assay uses one volume of 100  $\text{CH}_{50}$  of guinea pig complement added to one volume of test material. Working dilutions of hemolysin and complement to be used in the assay are determined previously by titration. Three

volumes of appropriate buffer are added to the two volumes and the material is allowed to react for one hour at  $37^\circ\text{C}$ . A control is run in which the volume of test material is replaced with one volume of appropriate buffer. After incubation the amount of complement present in each solution (control and test) is determined by titration. The control sample should contain no less than 85  $\text{CH}_{50}$  units. The value of complement present in the test sample ( $\text{CH}_{50}/\text{ml}$ ) is subtracted from the control value, and no more than 20  $\text{CH}_{50}$  units may be inactivated. In order to ensure a control value above 85  $\text{CH}_{50}$ , the initial complement titration is performed on complement that has been heated. Therefore more than 100  $\text{CH}_{50}$  units are actually present in all of the test and control samples. The release limit for this test is considered to be less than 20  $\text{CH}_{50}$  units complement per ml of product.

### Reactions

A reaction possibly mediated by spontaneous activation of the complement system was deemed to have occurred if any one or more of the following symptoms were present either during or up to four hours postinfusion: warmth, flushing, headache, fever, chills, anxiety, malaise, faintness, nausea, vomiting, muscle pains, abdominal cramps, chest pain, chest tightness, dyspnea, wheezing, tachycardia, or rash.

## RESULTS

### Reactions—Group 1

During the period under study, there were a total of ten possible complement-mediated adverse reactions (Table I).

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Table I. Spontaneously reported possible complement-mediated adverse reactions in group 1, March 1986 through December 1987.

Lot Number	AC Activity (CH <sub>50</sub> /ml) Method 1	Nature of Symptoms Reported
40B06	13.1	Chest tightness, dizziness, difficulty in breathing, lethargy
40B08	12.8	Headache after infusion
40P03	10.6	Vomiting, shortness of breath, abdominal pain after infusion
40P09	13.5	Generalized urticaria
40R02	14.2	Fever, increased pulse, chills, headache, general aches
40R03A	13.5	Flushing and fever after infusion
40S09	8.8	Dyspnea, hypotension, back pain, chills after infusion
40S10	8.5	(patient received two lots)
Not known	Not available	Headache, fever, malaise ten hours after infusion
Not known	Not available	Wheezing, chest tightness, dyspnea during rapid infusion
Not known	Not available	Wheezing, chest tightness, dyspnea during rapid infusion

AC = anticomplementary.

No lot had more than one such reaction; however, lot numbers for three reactions were not recorded and therefore no data are available. The reactions did not seem to occur with greater frequency with lots having higher AC activity.

During the one-year, nine-month study period, over 200 lots of IGIV, pH 4.25 were released. The distribution of the AC activity in these lots is shown in the figure. AC values ranged from 5.6 to 17.2 units CH<sub>50</sub>/ml. Most of the lots (80%) fell within the range 8.0 to 14.0 units CH<sub>50</sub>/ml.

**Reactions—Group 2**

There were a total of 15 reactions, four of which occurred during infusion (Table II). Although one of the four

reactions was considered severe, it did not necessitate discontinuing the infusion. Seven of the reactions, including the one classified as severe, were reported in association with the lot with low AC activity; all three reactions considered to be definitely related to the study drug infusion also occurred with this lot. There were five reactions with the lot with mid-range AC activity, and three reactions with the lot with high AC activity.

**Comparison of Two Assays of Anticomplementary Activity**

Ten lots of IGIV, pH 4.25 released for general usage were selected at random and their AC levels were compared using the two assays. The results are shown in Table III. It may be seen that according to

Percent of Total Lots

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PR 3025

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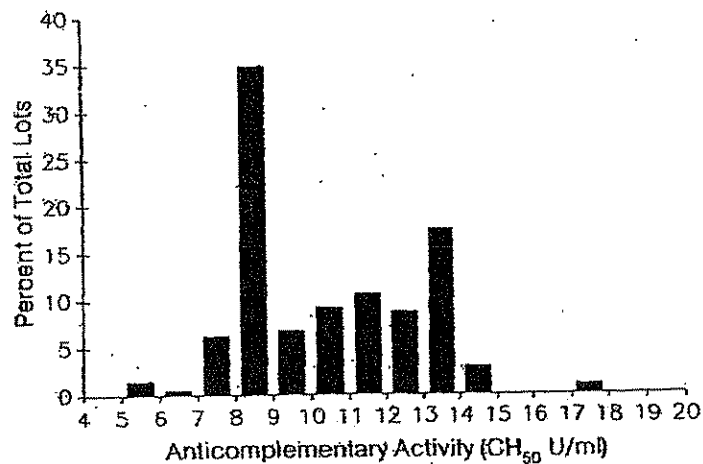


Figure. Anticomplementary activity of lots of IGIIV, pH 4.25 between March 1986 and December 1987 (Method 1).

Table II. Possible complement-mediated reactions in group 2 during the surveillance study.

Lot Number	AC Activity (CH <sub>50</sub> /ml) Method 1	Nature of Symptoms Reported
PR 3025	20.8	Rash after infusion Fever, lethargy after infusion Headache after infusion
PR 3032	15.6	Headache, seeing spots during infusion Abdominal cramps after infusion Headache after infusion Headache, abdominal cramps after infusion Headache after infusion
PR 3055	11.9	Chest tightness during infusion* Chest tightness, dyspnea during infusion* † Headache during infusion* Emesis after infusion Cough after infusion Emesis after infusion Emesis after infusion

AC = anticomplementary.

\* Only three of the reported reactions were considered definitely drug-related.

† Reaction classified as severe.



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Table III. Comparison of anticomplementary (AC) activity in ten randomly selected lots of IGIV, pH 4.25 by two AC assay methods.\*

Lot Number	AC Activity ( $\text{CH}_{50}/\text{ml}$ )	
	Method 1	Method 2
40B04	11.9	25.3
40B09	12.8	23.4
40B10A	11.9	24.7
40B11	13.5	28.6
40C04	17.2	28.5
40C05	14.3	25.5
40C07	10.4	21.6
40C08C	7.7	23.3
40C13A	8.6	26.0
40D02	8.2	25.1

\* With Method 1, an acceptable AC level is considered to be below 25 units  $\text{CH}_{50}/\text{ml}$ , while with Method 2 it is considered to be below 20 units  $\text{CH}_{50}/\text{ml}$ . Pearson product-moment correlation = 0.56 ( $P = 0.09$ ).

Method 1, all lots were considered to have acceptable AC activity, while with Method 2, all lots fell outside the limit for AC activity. None of these lots was associated with any spontaneously reported reactions even though one lot had the highest AC activity of all the lots released during the period under review.

The Pearson product-moment correlation between the results obtained with the two assays was found to be 0.56, which is not statistically significant ( $P = 0.09$ ).

## DISCUSSION

Spontaneously reported reactions are undoubtedly an underestimation, while the reverse is probably true for the definitive study in which every possible symptom ever associated with a complement-mediated reaction was taken to indicate such a reaction. Many of the reactions may have

been totally unrelated to the complement system, as is suggested by the absence of correlation between AC activity and the incidence of the reactions. In the definitive study, only one reaction was considered severe. There were no life-threatening reactions in either group of patients. There did not appear to be any correlation between the number and the severity of possible complement-mediated reactions with the level of AC activity in the lot used; in the definitive study there was almost a reverse correlation.

The data suggest therefore that the AC activity release limit and the assay used to measure the activity are reasonable and would not be associated with complement-mediated-type adverse reactions. The study showed that lots released in accordance with the specification limits defined by this assay did not show any significant incidence of complement-mediated adverse reactions.

The data also highlight the importance

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of using a designed (eg, intrav to be ass assay of / release k IGIV, pH activity 4 intravenc 2) was 1 tested in that were limit. Ye AC limit were ass tions. Fi between Method were use 4.25.

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of using an AC assay that is specifically designed and validated for the sample (eg, intravenous immunoglobulin) that is to be assayed. The Cutter Biological assay of AC activity (Method 1) used to release lots of IGIV was designed for IGIV, pH 4.25. When the assay of AC activity designed for a pepsin-treated intravenous immunoglobulin (Method 2) was used, all IGIV, pH 4.25 lots tested in this manner had AC activities that were well above the release cutoff limit. Yet none of these lots failing the AC limit in accordance with this assay were associated with any adverse reactions. Finally, there was no correlation between the assay of AC activity by Method 1 and by Method 2 when both were used to test AC levels in IGIV, pH 4.25.

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#### CONCLUSION

This study clearly demonstrates that the AC activity levels in IGIV, pH 4.25 are acceptable as defined by an assay validated to measure the levels in this preparation. This is also reflected in the safety of the preparation by the virtual absence of possible complement-mediated-type adverse reactions. The assay validated for a preparation finished by treatment with pepsin was unsuitable.

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## Serum Fe Ingestion

**Earl B. Daw**

Department of  
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### ABSTRACT

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I, Philip A. Rovner, hereby certify that on July 5, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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